

REMARKS

This Response is to the Office Action mailed April 1, 2005. Claims 1 to 4 and 6 to 9 are pending and are under consideration.

Applicants have submitted unexecuted copies of two Declarations under 37 C.F.R. §1.131. Upon receiving executed copies of the Declarations under 37 C.F.R. §1.131, Applicants will file a Supplemental Response with the executed Declarations. Applicants discussed this with the Examiner in a telephone call at which time the Examiner agreed to allow submission of a Supplemental Response with the executed Declarations. Applicants wish to thank the Examiner for their willingness to consider unexecuted copies of the two Declarations under 37 C.F.R. §1.131.

Regarding the Amendments

The amendments to claims 7 and 9 were made to address an informality or are supported by the specification. In particular, the amendments to claims 7 and 9, to delete reference to “skeletal muscle actin promoter and the muscle creatine kinase promoter/enhancer,” and “instructions,” respectively, were made to more clearly indicate the claimed subject matter. The amendment to claim 9 is also supported, for example, at page 20, line 28, to page 21, line 2. The amendments to claims 7 and 9 were not made in order to distinguish from any publication cited under 35 U.S.C. §102 or §103(a). Thus, the amendments do not add new matter and, as such, entry thereof is respectfully requested.

I. REJECTION UNDER 35 U.S.C. §102(e)

The rejection of claims 1 and 6 to 9 under 35 U.S.C. §102(e), as allegedly anticipated by Wilson *et al.* (U.S. Patent No. 5,866,552), is respectfully traversed. Allegedly, Wilson *et al.* “teaches a method for delivering and expressing a transgene delivered to an animal via recombinant AAV virus vector....which vectors comprise flanking ITR’s.” [see, Office Action, page 3]

Claims 1 to 4 and 6 to 9 are not anticipated by Wilson *et al.* (U.S. Patent No. 5,866,552). Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, submitted herewith are two Declarations under 37 C.F.R. §1.131, by Drs. Katherine High and Roland Herzog, inventors of the application, and accompanying four

laboratory notebook pages (Exhibit A, pages 1-4). The Declarations and Exhibit A indicate that recombinant Factor IX AAV vector was conceived and reduced to practice prior to September 6, 1996, the filing date of Wilson *et al.*

The first three laboratory notebook pages of Exhibit A are additional evidence of conception and reduction to practice. The fourth page of Exhibit A is a copy of the laboratory notebook page which was previously submitted with the two Declarations under 37 C.F.R. §1.131 of record, filed on May 18, 2004, and on June 5, 2001.

In brief, a pSSV9 vector was used to make the Factor IX AAV vector (see Declarations, paragraph 7; and Exhibit A, pages 1-3). pSSV9, also referred to as PSSV and psub201, is an AAV vector that contains two inverted terminal repeats flanking an Xba I site (see Declarations, paragraph 7). To corroborate that pSSV9 is an AAV vector with two inverted terminal repeats, submitted herewith are Exhibits B and C, publications by Lai *et al.* (Genetic Vaccines and Therapy 2:1 (2004)) and Miao *et al.* (J. Virol. 74:3793 (2000)), respectively. In Exhibit B, vector construction is described as follows: “[t]his cassette was inserted between the inverted terminal repeats of the serotype 2 rAAV plasmid pSSV9....achieved by blunt end ligation of the 3800 bp CMV.RPE65 cassette with the large fragment of pSSV9 following Xba I digestion.” (page 2, Methods, Virus preparation) In Exhibit C, rAAV vector is indicated to have been prepared as follows: “[p]reparation and characterization of rAAV-FIX from pSSV9-MFG-hFIX.” (page 3794, Materials and Methods) Exhibits B and C therefore corroborate that pSSV9, used to produce recombinant Factor IX vector, is an AAV vector that includes two inverted terminal repeats (Declarations, paragraph 7).

FIX intron 1 (claim 2) and a promoter/regulatory sequence were present in recombinant Factor IX AAV vector, as indicated on Exhibit A, page 3, lines 1 and 10 (“pCEP-FIX intron”). As also indicated on Exhibit A, page 3 (approximately lines 20-23), a 4 kb fragment was purified from Sal I digested/T4 polymerase treated “pCEP-FIX intron” for insertion into Xba I digested/T4 polymerase treated pSSV9 (Declarations, paragraph 8). The 4 kb fragment includes, *inter alia*, a promoter/regulatory sequence, a 1.4 kb portion of intron 1 (*i.e.*, from about 0.3 kb to about 1.7 kb in length; claim 3) and FIX cDNA (Declarations, paragraph 8).

A diagram of the complete recombinant Factor IX AAV vector is illustrated on Exhibit A, page 4, as “pSSV-F.IX intron” (Declarations, paragraph 9). The vector diagram shows the abbreviation “CMV” at the 5’ end of F.IX, a cytomegalovirus immediate early

promoter/enhancer (claims 1 and 7). The vector diagram also shows the abbreviation "SV40" at the 3' end of F.IX, a transcription termination signal (claims 1 and 9).

In view of the Declarations under 37 C.F.R. §1.131, by Drs. Katherine High and Roland Herzog, accompanying four laboratory notebook pages (Exhibit A) and corroborating publications (Exhibits B and C) indicating that recombinant Factor IX AAV vector was conceived and reduced to practice prior to September 6, 1996, Wilson *et al.* (U.S. Patent No. 5,866,552) is not available as prior art under 35 U.S.C. §102 against claims 1 and 6 to 9. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e), be withdrawn.

I. REJECTION UNDER 35 U.S.C. §103(a)

The rejection of claims 1 to 3 and 7 under 35 U.S.C. §103(a), as allegedly unpatentable over Wilson *et al.* (U.S. Patent No. 5,866,552), in view of Wang *et al.* (Human Gene Ther. 7:1743 (1996)) and Kurachi *et al.* (J. Biol. Chem. 270:5276 (1995)) respectfully traversed. Allegedly, Wilson *et al.* "teaches a method for delivering and expressing a transgene delivered to the muscle of an animal via recombinant AAV virus vector" as set forth in claim 1. Allegedly, Wang *et al.* "identifies a human factor IX minigene," and allegedly, Kurachi *et al.* discloses that "the XM1 minigene....comprises Factor IX 5' and 3' untranslated sequence and a first intron of approximately 1.4 Kb." [see, Office Action, page 7]

As set forth above, the Declarations under 37 C.F.R. §1.131 by Drs. Katherine High and Roland Herzog, accompanying four laboratory notebook pages (Exhibit A) and corroborating publications (Exhibits B and C) indicate that recombinant Factor IX AAV vector was conceived and reduced to practice prior to September 6, 1996. Accordingly, Wilson *et al.* (U.S. Patent No. 5,866,552) is not available as prior art under 35 U.S.C. §103(a) against claims 1 to 3 and 7. Consequently, Applicants respectfully request that the rejection under 35 U.S.C. §103(a), be withdrawn.

CONCLUSION

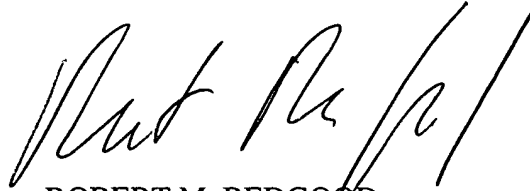
In summary, for the reasons set forth herein, Applicants maintain that claims 1 to 4 and 6 to 9 clearly and patentably define the invention, respectfully request that the Examiner reconsider the ground set forth in the Office Action, and respectfully request allowance of the claims now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 502212. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP

A handwritten signature in black ink, appearing to read 'Robert M. Bedgood', is written over the printed name.

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CERTIFICATION UNDER 37 C.F.R. §§ 1.8 and/or 1.10*

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I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: October 3, 2005



Signature

PATRICIA MUNOZ

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* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.